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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

EDWIN HARDEMAN, Plaintiff v. MONSANTO COMPANY and JOHN DOES 1-50. Defendant.	C.V. NO.: 3:16-cv-00525-VC **PLAINTIFF EDWIN HARDEMAN'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANT MONSANTO COMPANY'S MOTION TO DISMISS [NOTICE OF OBJECTION FILED CONCURRENTLY]** Hearing Date: April 7, 2016 Time: 10:00 a.m. Judge: Hon. Vince Chhabria Courtroom: 4, 17th Floor

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I. ISSUES TO BE DECIDED

1. Whether Plaintiff's warning claims impose requirements for labeling and packaging under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*
2. Whether the Restatement (Second) of Torts § 402A bars Plaintiff's non-warnings claims as a matter of law.

II. STATEMENT OF RELEVANT FACTS

Plaintiff Edwin Hardeman was diagnosed with Non-Hodgkins Lymphoma following decades of exposure to Monsanto's Roundup. Monsanto seeks to dismiss the claims of Mr. Hardeman for injuries from exposure to Roundup arguing that they are barred by express preemption and the Restatement (Second) of Torts § 402A. Monsanto's argument is legally and factually incorrect.

III. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7. U.S.C. § 136 *et seq*., does not expressly preempt Mr. Hardeman's claims. The Supreme Court in *Bates v. Dow Agrosciences LLC* made clear that FIFRA's preemption reach is narrow and applicable *only if* Monsanto can show that Mr. Hardeman's claims impose requirements for labeling or packaging that are "different from or in addition to" those imposed by federal law. 544 U.S. 431, 432 (2005). Plaintiff asserts two types of warning claims – claims not involving labeling or packaging or claims imposing requirements consistent with FIFRA's misbranding statute.

Second, Mosanto's argument that the Restatement (Second) of Torts § 402A bars Plaintiff's remaining claims is premature at the pleading stage. This argument attempts to revisit the central holding in *Bates* and should be summarily rejected. However, if the Court engages in analyses of comments k and j, Monsanto's argument must fail because it cannot establish the predicate requirements for protection on the face of the pleadings.

ARGUMENT

IV. PLAINTIFF'S FAILURE TO WARN CLAIMS DO NOT IMPOSE REQUIREMENTS IN ADDITION TO OR DIFFERENT FROM FIFRA.

FIFRA's preemption statute is narrow. FIFRA only preempts claims if they impose (1) requirements for labeling or packaging that are (2) "in addition to or different from" FIFRA requirements. *Adams v. United States*, 449 F. App'x 653, 658 (9th Cir. 2011) (citing *Bates*). Because Mr. Hardeman's failure to warn claims either do not involve labeling or packaging or simply parallel FIFRA's misbranding requirements, Plaintiff's claims are not subject to FIFRA's preemption statute, and Monsanto fails to carry its considerable burden of proving preemption. *Cortina v. Gooya Foods, Inc.*, 94 F.Supp.3d 1174 (S.D.Cal. 2015) (the party asserting preemption bears the burden of so demonstrating).

Monsanto can only prevail by establishing that FIFRA's preemption of Mr. Hardeman's claims is "the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("the purpose of Congress is the ultimate touchstone in every preemption case"). Where the text of a preemption provision is open to more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption." *Bates v. Dow Agrosciences LLC* 544 U.S. 431, 499 (2005). "This presumption against preemption leads us to the principle that express preemption statutory provisions should be given narrow interpretation." *Gordon v. Virtumundo, Inc*., 575 F.3d 1040 (9th Cir. 2009).

The Court must determine whether Mr. Hardeman's claims are substantively equivalent to FIFRA's requirements, focusing on the "elements of the common-law duty at issue." *Bates*, 544 U.S. at 445.

A. Monsanto fails to recognize that Mr. Hardeman's claims for failing to warn through advertising and marketing materials do not involve labeling or packaging.[1]

Mr. Hardeman's warning claims are not preempted under Section 136v(b) because they do not implicate labeling or packaging at all. Specifically, Plaintiff's claims fall into two

[1] Monsanto does not challenge Mr. Hardeman's claim for breach of implied warranty. This claim does not impose a "requirement for labeling or packaging" and escapes preemption. *See Wuebker v. Wilbur-Ellis Co*., 418 F.3d 883, 887 (8th Cir. 2005) (implied warranty of fitness for a particular purpose claim not preempted by FIFRA because it does not impose labeling or packaging requirements)

categories: Plaintiff alleges that Monsanto failed to warn of Roundup's adverse effects in violation of California law and FIFRA to (1) Mr. Hardeman, the agricultural, and medical communities via marketing or other communications and (2) the EPA.

The first category is not preempted because FIFRA's preemption clause does not extend to general promotional or marketing communications, as those types of communications do not involve "labeling or packing" requirements. *See Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc.*, 617 F.3d 207 (3d Cir. 2010) (sales literature is not a requirement for labeling or packaging). As a result, nothing in FIFRA preempts Mr. Hardeman's allegations that Monsanto failed to warn him and other entities, through advertising or promotional materials, of Roundup's carcinogenicity. Indeed, the Amended Complaint alleges that Monsanto made statements regarding product safety through marketing materials that differ from the statements contained in the product label. For example, Monsanto represented that that Roundup is "safe as table salt" or that "independent experts around the world.... agree that there is no evidence that glyphosate.... causes cancer." Am. Compl. ¶ 80, 99.[2] These statements regarding Roundup's safety made through marketing materials do not involve labeling requirements, and, therefore, are not subject to preemption.

Monsanto's brief does not address the second category of Mr. Hardeman's claims – namely, that Monsanto failed to alert the EPA of Roundup's toxic effects that are not identified on the product's label. This category is also not subject to preemption because the claims are not requirements for labeling or packaging nor is this a "fraud on the EPA" claim.[3] California imposes a state tort duty to warn on manufacturers, which can require the manufacturer to warn particular third-parties, and parallels FIFRA. *See Coleman v. Medtronic, Inc.,* 167 Cal.Rptr.3d 300 (Cal. Ct. App. 2014) (California imposes a state law duty to warn third parties); *Bates*, 544

[2] *See also* Am. Compl. ¶¶101-104; 123-124(a); 124(f); 124(i)-(p); 126-127(h); 173.

[3] Monsanto makes a passing reference to "fraud-on-the-agency claims." *See* Monsanto's Mem. Of Points and Authorities in Support of its Mot. To Dismiss, Doc. No. 18 ("Mot."). at n.21. Unlike *Nathan Kimmel, Inc. v. DowElanco,* Mr. Hardeman's claim does not arise solely from FIFRA, but instead a parallel state law duty.

U.S. at 439 citing 40 CFR §§ 159.184(a), (b) (2004) ("[M]anufacturers have a duty to report incidents involving a pesticide's toxic effects that may not be adequately reflected in its label's warnings."). Because Mr. Hardeman's claim imposes a parallel state duty, it is not a "fraud on the EPA" claim and escapes preemption. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 283 (2014); *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 765 (5th Cir.2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010).

B. Mr. Hardeman's warning claims relating to labeling or packaging are parallel to FIFRA requirements.

The second category of Mr. Hardeman's warning claims – claims that do touch upon labeling – are not preempted because they do not involve requirements that are in addition to or different from those imposed by FIFRA.[4] In fact, Monsanto has not identified a single requirement imposed by Plaintiff's claim that is inconsistent with FIFRA misbranding requirements.[5] *See Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757-58 (9th Cir. 2015) (rejecting preemption of California law under Proposition 65 because defendant failed to identify a contrary federal beverage labeling requirement); *Golden Wolf Partners v. BASF Corp.*, No. CV F 08-0618 LJO SMS, 2010 WL 5173197, at *8 (E.D. Cal. Dec. 13, 2010)

[4] In support of its argument, Monsanto cites two nonbinding and unpublished class action opinions from the Northern District of Indiana and the Northern District of Ohio. Both deal with the same flea and tick product, and both are distinguishable. In *Wilgus,* the Court found preemption because "throughout their Complaint, the Plaintiffs reference the inadequacy of the [product] labeling," claiming the product was un-merchantable when used *in accordance with* the label instructions and even quoted from the "defective" label as an element of their claims. 2013 WL 653707, at *5-6. In *Smith v. Hartz Mountain Corp* Plaintiffs alleged that FIFRA mandated warning was insufficient and that warnings *in addition to the FIFRA* requirements were necessary. 2012 WL 5451726, at *3. Mr. Hardeman makes no such claims and instead maintains that warning requirements exist independent of EPA's labeling decisions.

[5] *See Bates* 544 U.S. at 454 ("In undertaking a pre-emption analysis at the pleadings stage of a case, a court should bear in mind the concept of equivalence. To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding FIFRA requirement."); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757-58 (9th Cir. 2015) ("To the extent state law might be construed more broadly than federal law, the solution is not to prohibit state law suits altogether, but to 'instruct the jury on the relevant [federal] standards, as well as any regulations that add content to those standards'")

(FIFRA "prohibits only state-law labeling and packaging requirements that are 'in addition to or different from' the labeling and packaging requirements under FIFRA").

Indeed, common law claims that "enforce a federal requirement '[do] not impose a requirement that is different from or in addition to, requirements under federal law.'" *Bates*, 544 U.S. at 448 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 513 (1996) 513, O'Connor, J., concurring in part and dissenting in part). The crux of Monsanto's argument is that FIFRA requirements are indistinguishable from EPA labeling decisions; however, this argument was rejected by the Supreme Court in *Bates.* 544 U.S. at 438.

FIFRA imposes an independent requirement upon herbicide manufacturers to avoid misbranding. *Id* citing 7 U.S.C. § 136j(a)(1)(E). This duty exists separate from registration, and the EPA's approval of a label is no defense. *Id* citing 7 U.S.C. § 136(a)(f)(2). Indeed, it is a matter of black letter law that a manufacturer's failure to provide directions for use or warnings adequate to protect the health of users is a violation of FIFRA. *Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc*., 617 F.3d 207, 214 (3d Cir. 2010) citing 7 U.S.C. § 136(q)1. Specifically, FIFRA prohibits the sale or distribution of any pesticide that is misbranded. 7 U.S.C. § 136j(a)(1)(E). An herbicide is misbranded if:

> **(F)** the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or]
>
> **(G)** the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment[.] *Id.* at (E)-(F).

Similar to this requirement, to prevail on his state law claims, Mr. Hardeman must prove that Monsanto did not adequately warn of a risk that was known or knowable at the time of manufacture and distribution. *Carlin v. Superior Court*, 13 Cal 4th 1104, 1112 (1996). Because FIFRA already prescribes similar requirements, the warning at issue is not "different from or in addition to" and escapes preemption. *See e.g*., 40 CFR 156.10(h)(2)(i) ("Where a hazard exists to humans or domestic animals precautionary statements that describe the particular hazard,

route of exposure and precautions to be taken must appear on the label."). Moreover, Monsanto's argument that approval of the a label categorically bars warning claims ignores Section 136(a)(f)(2), which states, in relevant part, that "[i]n no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter." Therefore, an herbicide can be registered but still violate FIFRA by, among other things, failing to provide adequate warnings. 7 U.S.C. § 136j(a)(1)(E), (f)(2); *Bates*, 544 U.S. at 440 ("Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, ***manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements***.") (emphasis added). A common law claim that parallels FIFRA's labeling and misbranding requirements does not impose additional requirements because misbranding requirements exist independent of, and subsequent to, label approval. *See Bates,* 544 U.S. at 442 ("Nothing in the text of FIFRA would prevent a State from making the violation of a federal labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law. *The imposition of state sanctions for violating state rules that merely duplicate federal requirements is equally consistent with the text of § 136v.*") (emphasis added).

Because Monsanto does not identify the specific requirements it believes are "different from or in addition to" FIFRA, Monsanto urges the Court to create a categorical rule that *any* warning claim imposes a labeling requirement in addition to FIFRA. *See* Mot." at 6 ("136v(b) preempts any statutory or common law rule that would impose a warning requirement that diverges from EPA's labeling decision."). This argument has no merit, considering that this interpretation would eliminate all meaning from the latter part of 136v(b) ("in addition to or different from") and, taken to its logical end, would hold that herbicide manufacturers have no obligation to comply with FIFRA's misbranding or reporting provisions following registration. *See Bayview Hunters Point Cmty. Advocates v. Metro. Transp. Comm'n*, 366 F.3d 692, 700 (9th Cir. 2004), as amended on denial of reh'g and reh'g en banc (June 2, 2004) (A "basic rule of statutory construction is that one provision should not be interpreted in a way... that renders other provisions of the same statute inconsistent or meaningless."). The tautological result of

equating EPA labeling "decisions" to FIFRA "requirements" frustrates the statute and renders sections 136j(a)(1)(E) and 136a(f)(2) meaningless. *See Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc*., 617 F.3d 207, 214 (3d Cir. 2010) (finding parallel state law failure to warn claim was not preempted despite approval of label by the EPA).[6]

C. EPA's Glyphosate classifications are irrelevant

Monsanto seeks to dismiss Mr. Hardeman's claims on the basis of the "EPA's consistent findings that glyphosate is not carcinogenic." Mot. at 8-9. This argument is irrelevant for two reasons: First, courts interpreting FIFRA have rejected the notion that EPA findings of safety preempt state law tort claims. Even if the Court considers such findings, Monsanto's argument amounts to a "clear evidence" exception to preemption and Plaintiff must be permitted to present evidence in response. Secondly, Monsanto cites no authority to support the contention that findings as to a component part can insulate a manufacturer of a whole product from liability.

Monsanto's reliance upon EPA "safety" findings is irrelevant and improper.[7]. Classifications by the EPA do not constitute clear and manifest statements of Congressional intent that herbicides cannot be challenged as unsafe under state tort law. *Arias v. Dyncorp*, 517 F. Supp. 2d 221, 229 (D.D.C. 2007); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1539–40 (D.C.Cir.1984) (finding that EPA's determination that a product was safe for distribution under

[6] The Court should disregard *Mirzaie v. Monsanto Co*., as distinguishable. The *Mirzaie* decision turned upon impossibility preemption as the plaintiff in that case sought a permanent injunction striking language from the Roundup label. In the instant case, Monsanto's challenge is limited to express preemption. Moreover, the court's sweeping decision in *Mizraie* ignores that FIFRA's misbranding requirement exists independent of registration. No. CV 15-04361 DDP (FFMx), 2016 WL 146421 (C.D. Cal. Jan 12, 2016), *appeal docketed*, No. 16-55228 (9th Cir. Feb. 12, 2016); *See e.g. Bates* at 438 ("it is unlawful under the statute to sell a pesticide that is *registered* but *nevetheless misbranded*.")

[7] Monsanto's argument that the EPA's regarding the classification of glyphosate is based on extraneous matters and should be disregarded by the court pursuant to Fed. R. Civ. P. 12(d). Moreover, the EPA disclaimed in it's 1991 Group E glyphosate classification by stating that "[i]t should be emphasized that designation of an agent in Group E... *should not be interpreted as a definite conclusion that he agent will not be a carcinogen under any circumstances.*" (emphasis added) Am. Compl ¶ 47, n.7.

federal law and did not "pose an unreasonable risk to the normal user," did not preempt state tort claims challenging labeling).[8] Rather, that is a question for the fact finder to determine.

Although Monsanto cites no supporting authority, its contention that "EPA has rejected Plaintiff's State Law Argument" amounts to an challenge under the narrow "clear evidence" exception against preemption espoused in *Wyeth v. Levin*, 555 U.S. 555 (2009). While this exception has typically been limited in context to pharmaceutical drugs and devices, the analysis is instructive here. To establish preemption under the exception, the rule requires a manufacture produce "clear evidence" that an agency "would not have approved a change to [the] label." *Wyeth*, 555 U.S. at 571. Monsanto cannot establish this defense on the face of the pleadings.

Under this rule the Court must inquire whether "clear evidence' existed, at the time of Mr. Hardeman's injury, that *had Monsanto proposed* a change to its label, the EPA would have nonetheless rejected that proposal. In the usual case, the issue is "necessarily fact specific," which requires the Court to weigh evidence submitted by both sides in attempts to answer the hypothetical question. *In re Incretin-Based Therapies Prods. Liability Litig*., 2015 WL 6912689, *4 (S.D. Cal. Nov. 9, 2015) (citing *Koho v. Forest Labs, Inc.*, 17 F. Supp. 3d 1109, 1118 (W.D. Wash. 2014)). In *Wyeth* the Court identified four fact-specific considerations relevant to a clear evidence determination:

> (1) the manufacturer's knowledge and information concerning the risk in question. *Wyeth*, at 569-70
> (2) whether the manufacturer supplied the [agency] with an evaluation or analysis concerning the specific risks at issue;
> (3) whether the manufacturer attempted to give the kind of warning that plaintiff alleges was required under state law; and
> (4) whether the [agency] precluded the manufacturer from doing so.

Wyeth, 555 U.S. at 572-73.

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[8] The majority in *Bates* recognized that FIFRA contemplates that labels will evolve as new and relevant information surfaces. "*Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA*. Unlike the cigarette labeling law at issue in *Cipollone*, which prescribed certain immutable warning statements, *FIFRA contemplates that pesticide labels will evolve over time*, as manufacturers gain more information about their products' performance in diverse settings." *Bates*, 544 U.S. at 451 (emphasis added).

Defendant's evidence is insufficient to meet this requirement as a matter of law and Plaintiff is entitled to discover and present evidence to this Court. Similar to the FDA regulations at issue in *Wyeth*, FIFRA demands that the manufacturer, not the EPA, bears primarily responsibility for the content of its label. *Compare Wyeth*, 555 U.S. at 579 (holding that drug manufacturers, rather than the FDA, are primarily responsible for drug labeling); 7 U.S.C. § 136j(a)1(E) (manufacturers have a continuing obligation to adhere to labeling requirements); § 136a(f)(2) (registration is not a defense to misbranding); 136(a)(f)(1) (a manufacturer may seek approval to amend its label). Because Monsanto bears responsibility bears primary responsibility for its labels, the mechanism by which the label change is requested is material to the question of whether Monsanto can establish "clear evidence." *See In re: Zofran (Ondansetron) Products Liab. Litig.*, No. 1:15-MD-2657-FDS, 2016 WL 287056, at *3 (D. Mass. Jan. 22, 2016) (distinguishing citizen petition requests for label changes from requests by manufacturers). It does not follow that because the EPA came to an unprompted decision regarding glyphosate, that the agency would necessarily make the same decision had Monsanto proposed altering its Roundup label to strengthen the warnings. Thus, Monsanto cannot meet the "clear evidence" threshold because it cannot demonstrate that the EPA would have reached the same result had Monsanto submitted a label change request.

Additionally, for the "clear evidence" exception to apply, Plaintiff must first be entitled to discover and present to the Court what Monsanto knew about Roundup's propensity to cause cancer. This includes manufacturer's information concerning the risk in question, incident reports and "accumulating data" received by the company, and the company's communication with the FDA. *Wyeth*, 555 U.S. at 569-70. Consideration of the manufacturer's knowledge of the risk is necessary to a clear evidence determination because "manufacturers have superior access to information" about their products, "especially in the post marketing phase as new risks emerge" and thus "manufacturers, not the [agency], bear primary responsibility for their [product] labeling at all times." *Id.* at 578-79. Because Monsanto has not provided evidence as to its knowledge and information concerning the risks of Roundup's carcinogenicity, there is insufficient evidence for Plaintiff or the Court to perform this inquiry.

The importance of discovery on this point cannot be overstated. Monsanto ignores that every court to consider the clear evidence standard has done so in the context of a motion for summary judgment or a post-trial motion.[9] Because *Wyeth*'s clear evidence standard requires evidentiary findings based upon a developed record, the earliest juncture at which the standard can be addressed is after discovery and the record before the Court is sufficiently developed on the issue. Monsanto has cited no authority that the Court can properly consider its motion on the pleadings and Plaintiff has not found any case law supporting such a sweeping proposition.

Secondly, even if EPA classifications carried preemptive force, Monsanto cites no authority that agency determinations as to a component part insulate a whole product from liability. Here, Mr. Hardeman alleges that he was harmed by Monsanto's Roundup and specifically that Roundup is considerably more dangerous than glyphosate alone. Am. Compl. ¶¶ 48-50, 53-62, 124(e), 127(g). Accordingly, Monsanto can neither show that the EPA's classifications have preemptive force, nor that the EPA's classifications as to glyphosate alone render Monsanto's Roundup formulations, which contain glyphosate in combination with various surfactants, completely safe.

V. THE RESTATEMENT (SECOND) OF TORTS § 402A DOES NOT BAR ANY OF PLAINTIFFS DESIGN DEFECT CLAIMS AS A MATTER OF LAW

Monsanto's argument against Plaintiff's non-warning design defect claims attempts to revisit the central holding in *Bates* where the Supreme Court rejected the notion that defect claims function as disguised warning claims when federally approved and mandated labels are at issue. Even if applicable, Monsanto's arguments under § 402A of the Restatement (Second)

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[9] *See e.g., Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1236-37 (9th Cir.) cert. granted, judgment vacated sub nom. *L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497, 181 L. Ed. 2d 343 (2011) (reversed on other grounds based on *Pliva v. Mensing*) (considering whether the manufacturer "supplied the FDA with any 'evaluation or analysis concerning the specific dangers' posed by its drug); *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig*., No. 2436, 2015 WL 7075916, at *21 (E.D. Pa. Nov. 13, 2015) (considering the company's knowledge of the risk in question and observing that, "[a]s *Wyeth* made clear, the onus has always been on McNeil to ensure its label accurately reflects the risks of Extra Strength Tylenol"); *Koho v. Forest Labs., Inc*., 17 F. Supp. 3d 1109, 1118 (W.D. Wash. 2014) (considering whether defendant proposed any modifications to its drug label before the plaintiffs' injury)

of Torts fail as premature and/or lacking the predicate factual requirements necessary to invoke the defenses on *at the pleading stage.*

A. Monsanto's assumption that a federally approved label is a categorical bar against state law design defect claims is incorrect and unsupported by law.

In *Bates*, the Supreme Court implicitly considered and rejected the Monsanto's argument that non-warning design defect claims are barred by the Restatement (Second) of Torts § 402A. This argument is premised on the flawed assumption that a federally approved label is, categorically, a legally adequate warning barring all claims. Not only does Monsanto fail to cite any authority to support this sweeping proposition, but this assumption was rejected by the Supreme Court in *Bates*.[10] *See* e.g. *Bates*, 544 U.S. at 444 (rejecting the 5th Circuit's treatment of petitioner's defective design claims as "disguised claim[s] for failure to warn.").

Despite the prior adoption of the Restatement (Second) of Torts by Texas, the Supreme Court in *Bates* did not find the plaintiff's state law non-warning based claims barred on the grounds of an existing government approved label and other courts considering this issue have likewise declined to apply the rule Monsanto now seeks to advance. *See Bates*, 544 U.S. at 450 n. 25 (acknowledging that pesticides are inherently dangerous); *Ansagay v. Dow Agrosciences LLC*, No. CV 15-00184 SOM/RLP, 2015 WL 9582710 (D. Haw. Dec. 29, 2015) (Section 402A of the Restatement (Second) of Torts does not immunize manufacturers from liability from defect because of a federally approved label); *California Henley v. Phillip Morris Inc.*, 9 Cal. Rptr. 3d 29 (Cal. Ct. App. 2004) (federally mandated label does not preclude a product from failing California's consumer expectations test). Accordingly, this court should not adopt Monsanto's argument.

B. Comment k is inapplicable to Plaintiff's defect claims at the pleading stage

[10] Prior to the *Bates* decision, the state of Texas had adopted the Restatement (Second) of Torts § 402A. *See*, e.g., *FFE Transp. Services, Inc. v. Fulgham*, 154 S.W.3d 84, 87 (Tex. 2004) ("In *McKisson v. Sales Affiliates, Inc*., 416 S.W.2d 787, 788-89 (Tex. 1967), we adopted section 402A of the Restatement (Second of Trots on the scope of strict products liability.")

Even if applicable, Monsanto's reliance upon the Restatement (Second) of Torts § 402A comment k is premature at the pleading stage. Comment k is an *affirmative defense* that Monsanto cannot establish as a matter of law. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 , 2487 (2013) (comment k is an affirmative defense). Affirmative defenses may be upheld on a motion to dismiss only when they are established on the face of the complaint. *Morley v. Walker*, 175 F.3d 756, 759 (9th Cir.1999); *Jablon v. Dean Witter & Co.*, 614 F.2d 677, 682 (9th Cir.1980).

Comment k's protections have never been extended to herbicides as a matter of law and the reasoning underlying *Brown* does not support doing so here. *The* application of comment k to prescription drugs turned on prescription drugs' life saving potential, ability to reduce pain and suffering, and the independent safety buffer of a prescribing physician. *Brown v. Superior Court (Abbott Labs.),* 227 Cal. Rptr. 768, 773 (Ct. App.) review granted and opinion superseded, 723 P.2d 1248 (Cal. 1986) and aff'd sub nom. *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470 (1988). Courts following *Brown* have similarly emphasized these characteristics. *See Hufft v. Horowitz*, 4 Cal. App. 4th 8, 19, 5 Cal. Rptr. 2d 377, 384 (1992), modified (Mar. 17, 1992) ("society is well served by restricting available avenues of monetary recovery in exchange for increasing availability of *life-saving, suffering-alleviating* products") (emphasis added). Moreover, the rationale for extending comment k protection to drugs and medical devices is based, in large part, on the independent safety check provided by medical professionals and other learned intermediaries who can negotiate the risks and benefits involved in prescription drugs. *See, Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1397, 27 Cal. Rptr. 2d 589, 593 (1994) ("The conclusion is that the imposition of the condition of 'prescription' provides insulation between the manufacturer and the user such as to warrant elimination of the consumer protections afforded by strict liability."); *Ruiz-Guzman v. Amvac Chem. Corp*., 7 P.3d 795, 803 (Wash. 200), *opinion after certified question answered* 243 F.3d 549 (9th Cir. 2000) ("analogizing certified pesticide dealers and applicators to medical professionals is probably unwarranted."). Herbicides do not have life saving potential nor does an independent buffer exist in the present context. Accordingly, *Brown's* reasoning does not

support extending the blanket application of comment k to herbicides and the Court should decline to do so here.

Monsanto's attempt to compare the utility of Roundup to pharmaceutical drugs and medical products not only fails, but also underscores the impropriety of applying comment k at the pleadings stage. The defense is inapplicable because, outside of the context of prescription drugs, application of comment k is assessed on a case-by-case basis involving evidentiary determinations. *See Johnson v. Honeywell Int'l Inc.,* 179 Cal. App. 4th 549, 562 (2009) ("Application of comment k is based on public policy considerations."). Monsanto tacitly acknowledges this well-established rule by making an evidentiary argument touting the social utility of Roundup. Mot. at 13-15. Not only is an argument relying on extraneous matters improper at the pleading stage, the insuffi[11]ciency of Monsanto's argument is blatant. The very case law Monsanto relies upon, *Ruiz-Guzman,* expressly rejected the application of comment k to pesticides as a class, holding that application of comment k to pesticides is a factual determination. 7 P.3d at 803 ("[W]e hold that the question of whether a pesticide is governed by comment *k* is to be determined on a product-by-product basis, ***as opposed to a blanket exemption*** like that for medical products, it necessarily follows that ***the trier of fact should determine a pesticide's value to society relative to the harm it causes****.")* (emphasis added). A product qualifies for comment k protection only if its utility outweighs its risk, and a risk-utility determination is the jury's function. *See Ruiz-Guzman v. Amvac Chem. Corp*., 243 F.3d 549 (9th Cir. 2000) ("[i]t is the function of the jury to weigh the risks and utility of the pesticide").

C. Comment j does not insulate Monsanto from liability as a matter of law.

Even if applied, comment j does not preclude Plaintiff's design defect claims as a matter of law. Comment j requires a seller to give warnings when it "has knowledge, or in the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger." *See* Restatement (Second) of Torts § 402A. This

[11] When reviewing a motion to dismiss, a court may "consider only allegations contained in the pleadings, exhibits attached to the complaint, and matters properly subject to judicial notice." *Akhtar v. Mesa,* 698 F.3d 1202, 1212 (9th Cir. 2012).

defense fails because Monsanto cannot establish that it did not, or should not, have had knowledge of Roundup's danger *as a matter of law*. *See Am. Compl.* ¶¶ 44-62 *(*Monsanto had knowledge of Roundup's carcinogenic nature as early as the 1980s*).*

A warning does not negate the duty of safe design. "With the exception of a handful of misguided decisions that have misinterpreted comment j as negating the general duty of safe design, the vast majority of courts, some rejecting comment j explicitly on this point, hold that the separate forms of defect give rise to separate obligations that may independently support a products liability claim." *The Puzzle of Comment J*, 55 Hastings L.J. at 1393. Rather, California courts have consistently held that the duty to design a safe product is not abrogated by the presence of a warning. *Hansen v. Sunnyside Products, Inc*., 55 Cal. App. 4th 1497, 1517, 65 Cal. Rptr. 2d 266 (1997). In fact, even when a warning is adequate, it will not preclude liability under a design defect theory as a matter of law. *Id at 1517.* ("Whereas an adequate warning will avoid liability on a failure to warn theory, it is but one factor to be weighed in the balance in a design defect case."); *Id* at 1518 ("A manufacturer's placement of warnings on product may suffice to avoid liability under failure to warn theory, yet manufacturer may still be found liable under design defect risk/benefit analysis"); *Res-Care Inc. v. Roto-Rooter Servs. Co.*, 753 F. Supp. 2d 970, 995 (N.D. Cal. 2010) (Defendant "may be liable for failing to design a safe product *even if warnings rendered the danger obvious*.") (emphasis added); *Rogers v. Ingersoll-Rand Co*., 144 F.3d 841, 844 (D.C. Cir. 1998) ("It is thus not correct that a manufacturer may ... merely slap a warning onto its dangerous product, and absolve itself of any obligation to do more"). Because a Defendant may be liable for a defectively designed product, even when warnings are adequate, Monsanto's attempt to invoke comment j cannot preclude liability *as a matter of law*. *Putensen v. Clay Adams, Inc*., 91 Cal. Rptr. 319, 328 (Cal. Ct. App. 1970) (noting that in addition to a duty to design safe products, a manufacturer has a duty to provide adequate warnings).

CONCLUSION

For the foregoing reasons, this Court should DENY Monsanto's motion to dismiss in total.

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Respectfully Submitted

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